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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------|-------------|-----------------------|---------------------|------------------|
| 10/634,642 | 08/04/2003 | William Suttle Peters | 13634.4003 | 7193 |
| 34313 | 7590 | 05/18/2005 | EXAMINER | |
| ORRICK, HERRINGTON & SUTCLIFFE, LLP | | | ALTER, ALYSSA M | |
| 4 PARK PLAZA | | | ART UNIT | PAPER NUMBER |
| SUITE 1600 | | | | |
| IRVINE, CA 92614-2558 | | | 3762 | |
| DATE MAILED: 05/18/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/634,642 | PETERS ET AL. | |
| Examiner | Art Unit | | |
| Alyssa M Alter | 3762 | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 August 2003.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-27 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 04 August 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/20/04 & 2/14/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 19-22 and 27 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders these claims non-statutory. The examiner recommends changing "exits" and "placed in" to --adapted to exit the body-- and --adapted to be placed in--.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 18, 20-21 provides for the use of implantation and percutaneous exit from the body, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 19-21 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under

35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-20 and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Lederman (US 6,210,318). Lederman discloses a stented balloon pump system and method, which employs "a pumping balloon subsequently deployed within the stent such that the stent is interposed between the pumping balloon and the body passageway within which the pumping balloon is operatively positioned, as seen in figure 1.

As to claims 4-8 and 24-25, "expansion of the stent is often effected by inflation of an angioplasty balloon or the like within the stent, to force radial expansion of the stent until it contacts and/or adheres to the wall of the body passageway. In one embodiment of the present invention, pumping balloon 106 may be inflated within radially contracted stent 104, expanding stent 104 until it contacts the inner wall of descending aorta 152 and embeds itself therein. In an alternative embodiment, another balloon may be used for this purpose. If desired, the above noted stented aortic graft systems can be used, wherein the stent provides a scaffold-like support which can be

expanded by outward radial pressure provided by a balloon or by virtue of self-expanding shape-memory materials such as nickel titanium alloy formulated to transform from martensitic to austenitic phase at body temperature, following delivery by catheter to the desired site" (col 8-9, lines 67 and 1-16).

As to claims 9-12 and 15, Lederman discloses, in col. 8, lines 18-56, numerous vascular and intra-aortic stents. Such examples of stent embodiments are: reinforcing stent constructed from a single elongated wire, stent formed of half-round wire, collagen-coated stent, cylindrical, open-ended intra coronary stent, radially-expandable stent, balloon-expandable, crush-resistance locking stent, compressive stent, intravascular radiallyexpandable stent, expandable intraluminal graft, expandable polymeric stent, self-expanding prosthesis stent and a stent with a thin graft material covering or lining, such as thinly woven polyester yarns shaped into tubular coverings to form aortic stented grafts of the type commercially available.

As to claims 13-14, figures 2A-2B and 3A-3B reveal the stent with the balloon extended around the full circumference of the stent frame. Since the balloon extends around the entire circumference of the stent lumen, the examiner considers balloon to extend around a part of the circumference of the stent lumen.

As to claims 16-17, figures 2A-2B displays "hole(s) 204 and 208 may be dimensioned to effectuate inflation and deflation of a desired rapidity. Any appropriate fluid or gas may be used to inflate and deflate pumping balloon 14 and balloon valve 15. In a preferred embodiment, however, a low molecular weight gas such as argon is

utilized"(col. 7, lines 30-33). The examiner considers the Control drive mechanism 112 to be a fluid pressure source since it controls the pressure inside the pumping balloon.

As to claim 17, It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

As to claims 18-20 and 26, since the "balloon pump 102 is attached to a multi-lumen catheter 110, which is brought outside the body through the arterial tree, such as the subclavian artery 158, as shown in FIG. 1"(col. 5, lines 29-32), there is inherently an aperture in the artery to facilitate the catheter being "brought outside the body". In addition, the subclavian artery is located in the thorax and therefore is connected thoracoscopically.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 21, 22 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lederman (US 6,210,318) in view of Kiyota et al. (US 5,453,076). Lederman discloses the claimed invention except for the sternotomy. Kiyota et al. teaches in column 12, lines 11-14, that it is known to surgically insert and arrange an internal cardiac assist apparatus between the sternum and the pericardium. It would have been

obvious to one having ordinary skill in the art at the time the invention was made to modify the placement of the cardiac support system as taught by Lederman since such a modification would alter the surgical procedure to meet specific patient needs.

As to claim 22, since "the shape-memory materials can be alloyed for later removal by intraluminal catheter flush with cooled saline to induce reversion to a reduced profile at martensitic phase for ease of withdrawal"(col. 9, lines 16-19), the catheter obviously has a liquid carrying tube.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Franchi (US 6,030,336) discloses a pressure generator for a counterpressure cardiac assistance device.
2. Schiff (US 4,515,587) discloses an IAB having apparatus for assuring proper balloon inflation and deflation.
3. Peters et al. (US Patent Publication 20040073080 A1) discloses a heart assist devices, systems and methods with an inflatable means for engaging and compressing the aorta.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alyssa M Alter

Alyssa M Alter
Examiner
Art Unit 3762

[Signature]
JEFFREY R. JASTRZAB
PRIMARY EXAMINER
5/16/05